IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HIKMA PHARMACEUTICALS USA INC.,	)	
Defendant.	)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Hikma Pharmaceuticals USA Inc. ("Hikma"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Hikma's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Hikma seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Victoza® prior to the expiration of United States Patent Nos. 8,579,869 (the "'869 patent"), 7,762,994 (the "'994 patent"), 8,114,833 (the "'833 patent") and 9,265,893 (the "'893 patent"), which cover inter alia, Victoza® and/or its use.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

3. Plaintiff Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly owned subsidiary of NNAS.

4. On information and belief, Defendant Hikma is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. On information and belief, Hikma is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Hikma by virtue of, inter alia, its presence in Delaware, being a Delaware corporation; having conducted business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court; having taken advantage of the rights and protections provided by this Court, including having filed complaints in this jurisdiction (*see, e.g.*, Complaint, *Hikma Pharm. USA Inc. v. Micro Labs Ltd.*, No. 19-883 (D. Del. May 10, 2019); Complaint, *Hikma Pharm. USA Inc. v. Aurobindo Pharma Ltd.*, No. 21-228 (D. Del. Feb. 18, 2021)); and having engaged in systematic and continuous contacts with the State of Delaware.

7. On information and belief, Hikma intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Hikma's Product, directly or indirectly, throughout the United States and in this District. Hikma's filing of Hikma's ANDA confirms this intention and further subjects Hikma to the specific personal jurisdiction of this Court.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

9. On November 12, 2013, the United States Patent and Trademark Office issued the '869 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '869 patent.

10. On July 27, 2010, the United States Patent and Trademark Office issued the '994 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '994 patent.

11. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '833 patent.

12. On February 23, 2016, the United States Patent and Trademark Office issued the '893 patent, entitled "Injection Button," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '893 patent.

VICTOZA®

13. NNI holds approved New Drug Application No. 022341 (the "Victoza® NDA") for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Victoza®.

14. The claims of the patents-in-suit cover, inter alia, Victoza® and/or its use.

15. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '869, '994, '833, and '893 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Victoza®.

HIKMA'S ANDA

16. On information and belief, Hikma submitted ANDA No. 215503 ("Hikma's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Hikma's Product").

17. On information and belief, Hikma's ANDA refers to and relies upon the Victoza® NDA and contains data that, according to Hikma, demonstrate the bioequivalence of Hikma's Product and Victoza®.

18. By letter to NNI and NNAS, dated November 11, 2021 (the "Notice Letter"), Hikma stated that Hikma's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '869, '994, '833, and '893 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hikmas's Product (the "Paragraph IV Certifications"). Hikma attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certifications. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,579,869

19. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-18 of this Complaint.

20. Hikma has infringed the '869 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Hikma's ANDA, by which Hikma seeks approval from the FDA to manufacture, use, offer to sell, and sell Hikma's Product prior to the expiration of the '869 patent.

21. Claims 1-6 of the '869 patent are directed to a needle mount. Hikma's manufacture, use, offer to sell or sale of Hikma's Product within the United States, or importation of Hikma's Product into the United States, during the term of the '869 patent would infringe claims 1-6 of the '869 patent.

22. Novo Nordisk will be harmed substantially and irreparably if Hikma is not enjoined from infringing the '869 patent and/or if the FDA is not enjoined from approving Hikma's ANDA before the '869 patent expires.

23. Novo Nordisk has no adequate remedy at law.

24. Hikma was aware of the '869 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,762,994

25. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-24 of this Complaint.

26. Hikma has infringed the '994 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Hikma's ANDA, by which Hikma seeks approval from the FDA to manufacture, use, offer to sell, and sell Hikma's Product prior to the expiration of the '994 patent.

27. Claims 1-8 of the '994 patent encompass a mounting system for mounting two different needle arrangements. Hikma's manufacture, use, offer to sell or sale of Hikma's Product within the United States, or importation of Hikma's Product into the United States, during the term of the '994 patent would infringe claims 1-8 of the '994 patent.

28. Novo Nordisk will be harmed substantially and irreparably if Hikma is not enjoined from infringing the '994 patent and/or if the FDA is not enjoined from approving Hikma's ANDA before the '994 patent expires.

29. Novo Nordisk has no adequate remedy at law.

30. Hikma was aware of the '994 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,114,833

31. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-30 of this Complaint.

32. Hikma has infringed the '833 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Hikma's ANDA, by which Hikma seeks approval from the FDA to manufacture, use, offer to sell, and sell Hikma's Product prior to the expiration of the '833 patent.

33. Claims 1-15 of the '833 patent are directed to GLP-1 formulations. Claims 16-31 are directed to methods for preparing such formulations or methods of reducing deposits or reducing clogging by replacing the isotonicity agent in a formulation with propylene glycol. Hikma's manufacture, use, offer to sell or sale of Hikma's Product within the United States, or importation of Hikma's Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent. In the Notice Letter, Hikma has not contested infringement of any claims of the '833 patent.

34. Novo Nordisk will be harmed substantially and irreparably if Hikma is not enjoined from infringing the '833 patent and/or if the FDA is not enjoined from approving Hikma's ANDA before the '833 patent expires.

35. Novo Nordisk has no adequate remedy at law.

36. Hikma was aware of the '833 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,265,893

37. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-36 of this Complaint.

38. Hikma has infringed the '893 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Hikma's ANDA, by which Hikma seeks approval from the FDA to manufacture, use, offer to sell, and sell Hikma's Product prior to the expiration of the '893 patent.

39. Claims 1-6 of the '893 patent are directed to a push button connection for an injection device. Hikma's manufacture, use, offer for sale or sale of Hikma's Product within the United States, or importation of Hikma's Product into the United States, during the term of the '893 patent would infringe claims 1-6 of the '893 patent.

40. Novo Nordisk will be harmed substantially and irreparably if Hikma is not enjoined from infringing the '893 patent and/or if the FDA is not enjoined from approving Hikma's ANDA before the '893 patent expires.

41. Novo Nordisk has no adequate remedy at law.

42. Hikma was aware of the '893 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Hikma and respectfully requests the following relief:

A. A judgment that Hikma has infringed the '869 patent;

B. A judgment that Hikma has infringed the '994 patent;

C. A judgment that Hikma has infringed the '833 patent;

D. A judgment that Hikma has infringed the '893 patent;

E. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Hikma's ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '869, '994, '833, and '893 patents, including any extensions, adjustments, and exclusivities;

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Hikma, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Hikma's Product within the United States, or importing Hikma's Product into the United States, prior to the expiration of the '869, '994, '833, and '893 patents, including any extensions, adjustments, and exclusivities;

G. If Hikma commercially manufactures, uses, offers to sell, or sells Hikma's Product within the United States, or imports Hikma's Product into the United States, prior to the expiration of the '869, '994, '833, and '893 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

H. An award of attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

I. An award of costs and expenses in this action; and

J. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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December 21, 2021